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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: Based on PCT/JP2004/014475
Filed: Intl. Filing 01 OCT 2004
1st Inventor: T. ASAKAWA
For: Agent for Treating Diabetes
Atty. Dkt. No. 3197 USOP

Art Unit: tba
Examiner: tba
Allowed:
Batch:
Paper No.:

Information Disclosure Statement

MAIL STOP PCT
P.O. Box 1450
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §1.56, 1.97 and 1.98, Applicants request consideration of the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B. A legible copy of each listed reference is herewith being provided to the Examiner.

This Information Disclosure Statement is being submitted within 3 months of the filing date of the above-identified application, and before the mailing date of the first Office Action on the merits, thus, no certification or fee is required.

Applicants respectfully request that the listed documents be considered by the Examiner and formally be made of record in the present application and that an initialed copy of the attached forms be returned in accordance with MPEP §609.

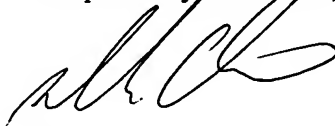
Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney.

Dated: 3/28/06

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Takeda Pharmaceuticals North America, Inc.
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Respectfully submitted,



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Attorney for Applicants
Customer No. 23115

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| Sheet | 1 | of | 2 |
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|------------------------|----------------------------|
| Application Number | Based on PCT/JP2004/014475 |
| Filing Date | Intl. Filing 01 OCT 2004 |
| First Named Inventor | T. Asakawa |
| Art Unit | tba |
| Examiner Name | tba |
| Attorney Docket Number | 3197US0P |

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ^o |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | A1 | EP 1537880 A1 | 06-08-2005 | Takeda Pharmaceutical Co. | | |
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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1P20B351P00000 10 MAR 2006

PTO/SB/08B (08-03)

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| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | Based on PCT/JP2004/014475 |
| | | Filing Date | Intl. Filing 01 OCT 2004 |
| | | First Named Inventor | T. Asakawa |
| | | Art Unit | tba |
| | | Examiner Name | tba |
| Sheet 2 | of 2 | Attorney Docket Number | 3197US0P |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | A2 | J. LARSEN, MD., et al., "Glucagon-Like Peptide-1 Infusion Must be Maintained for 24 h/day to Obtain Acceptable Glycemia in type 2 Diabetic Patients Who are Poorly Controlled on Sulphonylurea Treatment", Diabetes Care, (August 2001), 24(8): 1416-1421 | |
| | A3 | M.A. NAUCK, MD., et al., "Influence of Glucagon-Like Peptide 1 on Fasting Glycemia in Type 2 Diabetic Patients Treated with Insulin After Sulfonylurea Secondary Failure", Diabetes Care, (November 1998), 21(11): 1925-1931 | |
| | A4 | V. TRISCHITTA, et al., "Comparison of Combined Therapies in Treatment of Secondary Failure to Glyburide", Diabetes Care, (April 1992), 15(4): 539-542 | |
| | A5 | G. FANGHANEL, MD., et al., "Metformin's Effects on Glucose and Lipid Metabolism in Patients with Secondary Failure to Sulfonylureas", Diabetes Care, (November 1996), 19(11): 1185-1189 | |
| | A6 | H. KIYONO, et al., "Analysis of Functional Relation of Pancreatic Beta-Cell ATP-Sensitive K ⁺ Channels and Sulfonylurea Receptor, and Development of Oral Antidiabetic Drug Based on New Action Mechanism", Suzuken Memorial Foundation, (2001), pages 147-149, English Translation attached. | ✓ |
| | A7 | K. YAMADA, "Appropriate Use and Combined Use of Oral Hypoglycemic Agents, (2002), Vol. 36, pp. 292-296, English Translation of Tonyobyogaku no Shinpo attached. | ✓ |
| | A8 | J. KAN, et al., "The Effect of Ultra-Rapid-Acting Insulin Secretagogue, Nateglinide (Na), in Patients with Type 2 Diabetes That Seems to Be Secondary Ineffectiveness of SU Drugs", The Journal of the Japan Diabetic Society, (2000), 43 (Supple. 1), p. S-120, English Translation attached. | ✓ |
| | A9 | K. MIMURA, et al., "Experience of Use of Rapid-Acting Postprandial Hypoglycemic Drug (Nateglinide) in Type 2 Diabetic Patients Who Showed Secondary Effectiveness of Sulfonylurea Drugs", Nippon Taishitsugaku Zasshi, (2001), 63(1-2): 52; English Translation attached. | ✓ |
| | A10 | Y. KITAHARA, et al., "A Rapid-Onset/Short-Duration Insulin Secretagogue as a Physiologic Postprandial Blood Glucose Regulator", Saibo (Cells), 2000, 32(12): 480-483; English Translation Attached | ✓ |
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|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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